Assessment of Health-Related Quality of Life Among Male Patients With Controlled and Uncontrolled Hypertension in Semi Urban India

Mansi Patil, PhD[1] (iD), Radhika Prashant Hedaoo, PhD[2],
Rohan Pravinbhai Shah, MPH[3], Syed Mohammad Tauseef, PhD[4],
Roy Rillera Marzo, PhD[5,6], Siew Mooi Ching, MD[7,8],
and Gavin Lambert, MS[9] (iD)

Abstract

The burden of hypertension has been growing over recent decades. In addition to risk of stroke and cardiovascular disease development, data indicates that hypertension may also pose a hazard to the quality of life (QoL) of individuals. Patient reported outcomes such as QoL are often overlooked, with physicians and healthcare professionals not routinely evaluating or customizing treatments according to QoL. In this study we aimed to assess the QoL of hypertensive men (n = 500) undergoing treatment who visited a charitable hospital in Pune, India. Clinic blood pressure was determined and the Mini Cuestionario de Calidad de Vida en Hipertensión Arterial (MINICHAL) scale was used to assess the health-related (HR)-QoL of patients. More than half of the participants (62%) had uncontrolled hypertension, with a mean systolic blood pressure (BP) of 151 ± 12 mmHg and diastolic blood pressure of 87 ± 6 mmHg as compared to those with controlled blood pressure (mean systolic blood pressure 123 ± 6 mmHg and diastolic blood pressure 84 ± 5 mmHg; $P < .01$ for both). Predominantly the participants were overweight with body mass index (BMI) of those with uncontrolled hypertension being greater than those with controlled blood pressure (28.4 ± 3.3 kg/m² vs 23.3 ± 2 kg/m², $P < .01$). A reduced QoL was observed for participants with uncontrolled hypertension (overall score 41 ± 5) as compared to those with controlled blood pressure (35 ± 4, $P < .001$). This was evident on both the mental plane [2.8 ± 2.5 (95% CI = 2.3-3.1) vs 4.1 ± 3.2 (95% CI = 2.5-3.3)] and somatic domain [3.4 ± 3.2 (95% CI = 3.0-4.0) vs $4.7.4 \pm 3.5$ (95% CI = 3.1-4.5)] where the QoL was poorer ($P < .001$) for the uncontrolled hypertensive group. Poorer QoL was observed for people with uncontrolled hypertension. This study indicates that the QoL in patients with uncontrolled hypertension attending an outpatient clinic in India is worse than those with controlled blood pressure. Future studies need to be undertaken to ascertain whether an impaired QoL impacts the outcomes associated with high blood pressure.

Keywords

health related quality of life, hypertension, patient reported outcomes, blood pressure, MINICHAL scale, psychosocial factors, self-reported health

What do we already know about this topic?
Hypertension is a chronic condition that affects the quality of life of individuals.

How does your research contribute to the field?
Uncontrolled hypertension leads to poorer quality of life as compared to controlled hypertension in a semi-urban Indian population.

What are your research's implications toward theory, practice, or policy?
It is crucial to consider the QoL of individuals and tailor the therapy and interventions to improve the general well-being of individuals, which could potentially improve medication compliance.

Introduction

Cardiovascular diseases (CVD) are recognized as the leading causes of morbidity and mortality worldwide, with rates rising in developing countries. Indeed, India has seen a sharp increase in CVDs in the last two decades.[1,2] The age-standardized CVD mortality in India is 272 per 100 000 compared with global rates of 235 per 100 000.[3]

Hypertension is the leading cause of cardiovascular disease.

Indeed, hypertension is the leading cause of cardiovascular disease and the prevalence of hypertension has grown globally, including on the Indian subcontinent, and has paralleled the shift toward westernized culture, with increase in unhealthy dietary patterns, reduction of physical activity levels and a rising occurrence of overweight and obesity.[4-7] Worldwide around 7.5 million people die due to the consequences of hypertension.[8] In Maharashtra, the prevalence of hypertension was 25%[9] which is almost similar to the national prevalence of 30% across India.[10] In addition, the study reported that the prevalence of controlled blood pressure in India is only 12%.[11] This high rate of uncontrolled blood pressure may be associated with a poor health-related quality of life (HRQoL) among hypertensive patients compared to patients with controlled blood pressure.[12,13]

Health-related QoL (HR-QoL) is a measure of well-being which is based on an individual's social, economic, and subjective perceptions.[14] The World Health Organization (WHO) defined QoL as "an individual's perception of their position in life, in the context of culture and system of values in which they live and in relation to their goals, expectations, standards and concerns."[14,15] The variation in HR-QoL has been observed across multiple domains including physical, social, and psychological aspects.[16,17] Various studies have examined a relationship between hypertension and QoL using the MINICHAL scale, a QoL tool specifically designed for use in hypertensive patients. The studies also reported that improved medication adherence, better access to healthcare services and higher levels of physical activity were associated with higher QoL as measured by the MINICHAL scale. The association between blood pressure BP and QoL is not clear. While some studies have shown worse QoL in patients with hypertension, others have not.[17-20] Differences in QoL may be associated with lack of blood pressure BP control, whereby uncontrolled hypertension is associated with leads to poorer quality of life, particularly in the mental health domain.[21] Improvement in mental health components of QoL in patients with resistant hypertension has been shown to be associated with better blood pressure reduction following renal denervation.[22,23] Given the differences in geography, demography, and societal influences. It remains unknown whether this the association between blood pressure control and QoL is evident in the outpatient setting that we observed could be influenced by geography or sociodemographic variables remains to determined.[17-19] Poor quality of life not only may impair adherence among hypertensive patients, which may lead to uncontrolled blood pressure. Although previous studies have examined the impacts of various demographic and clinical factors on HRQoL in patients with hypertension[17-20] fewer investigations have been conducted to examine the impact of blood pressure control status on the HRQoL in Maharashtra. Therefore, it was necessary to compare the HRQoL between hypertensive patients with and without blood pressure control. The aim of this study was to compare QoL among male hypertensive patients with and without blood pressure control.

Methods

Study Design and Sampling

This investigation was a cross-sectional observational study with a sample size of 500 male patients with hypertension who were drawn from a clinic at a charitable hospital in Chinchwad (Pune, India). We recruited the first 500 patients who agreed to participate. The Cardiac Department regularly sees 50 number of follow-up patients with hypertension daily. The sample size for the mediation was calculated using G-power 3.1, a sample size calculator based on mean score of HRQoL of 3.59 ± 0.41 among hypertensive patients with and without blood pressure controlled.[11] The estimated sample size was 440 with 97% power, 95% confidence

[1]Asha Kiran Jubilee Hope Centre Hospital, Chinchwad, Pune, India
[2]Symbiosis International University, Pune, India
[3]KEM Hospital Research Centre, Pune, India
[4]University of Petroleum & Energy Studies, India
[5]Management and Science University, Shah Alam, Selangor, Malaysia
[6]Monash University Malaysia, Selangor, Malaysia
[7]Universiti Putra Malaysia, Serdang, Malaysia
[8]Sunway University, Selangor Darul Ehsan, Malaysia
[9]Swinburne University of Technology, Hawthorn, Australia

Corresponding Authors:
Mansi Patil, Department of Nutrition, Asha Kiran Jubilee Hope Centre Hospital, Balaji Chowk, Kalbhor Nagar, Near Mother Teresa Home, Chinchwad, Pune, Maharashtra 411019, India.
Email: drpatilmansi@gmail.com

Roy Rillera Marzo, Management and Science University, International Medical School, Shah Alam, Selangor 40460, Malaysia.
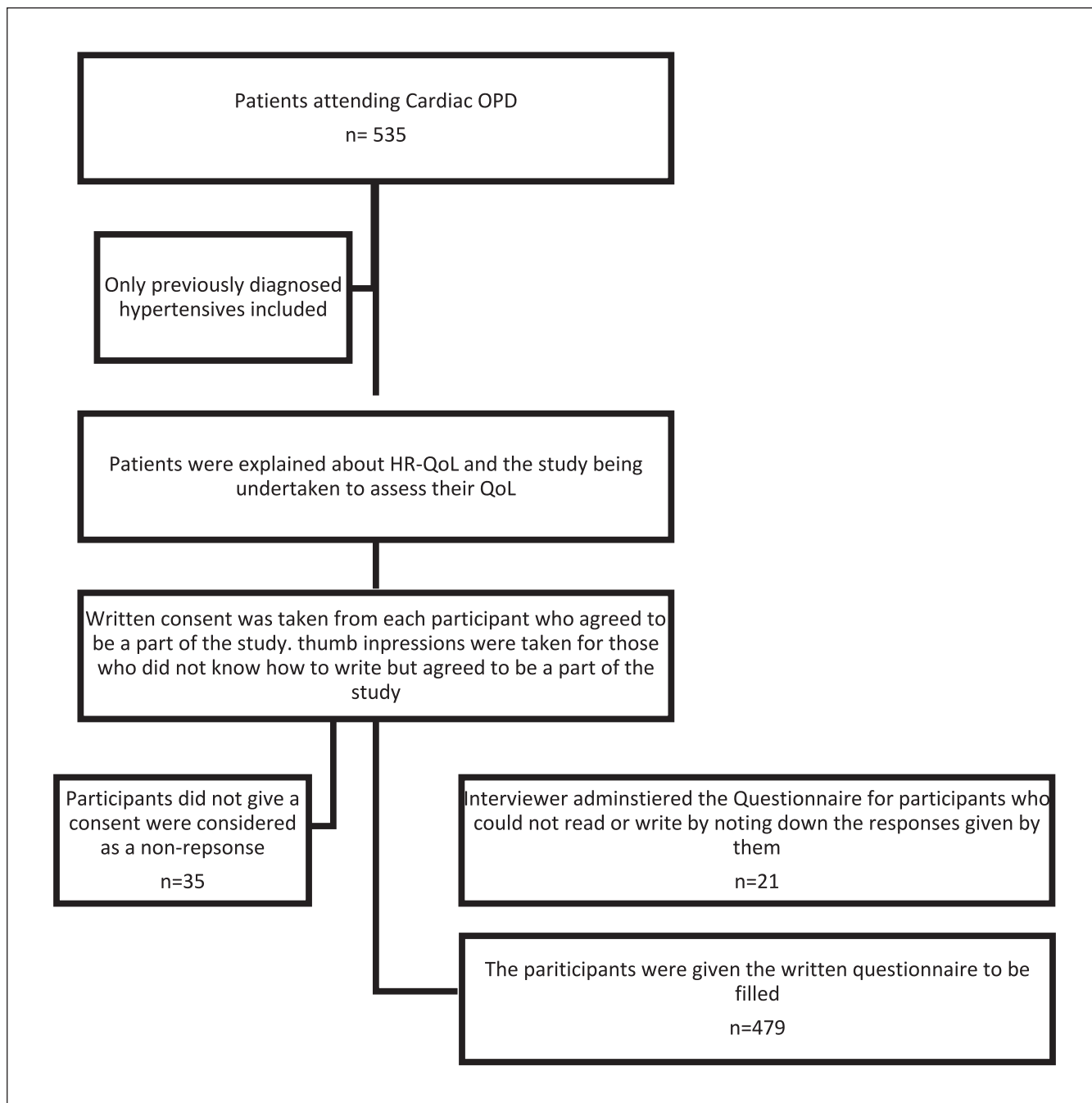Email: roy.marzo@monash.edu

Figure 1. Recruitment of patients for the study.

interval, and *P*-value .05. The final sample size was 488 after accounting for the 10% non-response rate. 95% confidence interval, and *P*-value .05. The final sample size was 488 after accounting for a possible 10% non-response rate.

The study was carried out using the convenient sampling technique. Participants were drawn from the Cardiac out-patient department (OPD) which has an attendance, on average, of 50 patients per day. Patients, who attended the hospital, registered as new or follow-up patients with the hospital's Cardiac OPD.

Five hundred previously diagnosed hypertensive patients (Figure 1) and currently on medication who attended the clinic received a patient information sheet and were asked to seek their consent to participate in this study. Consent was given either in writing or by thumbprint for those who were unable to write. The data collection was undertaken from April 2016 to March 2017. The study was approved by Asha Kiran JHC Hospital Ethics Committee (EC), Chinchwad Pune (EC reference number: AJH2018/0819/301).

Inclusion and Exclusion Criteria

Male patients aged 20 to 60 years with previously diagnosed hypertension who were on anti-hypertensive medications. Participants who have attended Cardiac OPD of the hospital for at least 6 months on a regular basis were considered eligible for the study. Participants with other diagnosed/known systemic illness for example, Diabetes, COPD, Asthma, and psychotic illness and who were on anti-psychotic medications, anti-diabetic drugs, or anti-inflammatory drugs were excluded from the study. Considering the cardiac OPD at the huge inflow of hospital sees mainly male patients as compared to female patients a convenience sample design involving, and hence males were considered in this study. Although the author states a limitation of the study for selecting only male participants. The study was considered for the study carried out in a cardiac OPD which conducted hypertension clinic, all the patients visiting the clinic were hypertensive.

Tools Used for Data Collection

The Mini Cuestionario de Calidad de Vida en Hipertensión Arterial (MINICHAL) is a scale that has been developed to assess the HR-QoL in patients with hypertension and has been used in various studies.[18] The MINICHAL scale is structured, closed ended questionnaire in which each item is scored on a four point adjectival scale from "No, not at all" to "Yes very much" to derive an average score used specifically for assessing the HR-QoL in patients with hypertension. It has been demonstrated to be an effective tool for quantifying the HR-QoL of hypertensive patients in population-based studies.[18] This scale has 17 items, of which there are 9 items relating to mental wellbeing (score of 0-27) and 7 items on the somatic plane (score of 0-21). The overall impact of hypertension and the person's level of adjustment to raised blood pressure was assessed in the last item of the questionnaire. Total points allotted range between 0 (signifying best level of health) and 51 (signifying worst level of health).

The MINICHAL scale was translated in vernacular languages (Marathi and Hindi) and re-translated to ensure content validity. The questionnaire has been designed for self-administration but most of the patients required delivery as a structured interview to reduce the variability in the understanding of the questions. The responses were collected in the interviews, based on the experiences of the participants over the last 7 days. The questionnaire took approximately 20 min to deliver. As the questionnaires were converted in local language, the reliability of the questionnaire was checked using Crohnbach alpha coefficient on a sample of (n = 30).

Cronbach's alpha co-efficient for the MINICHAL scale in Hindi for the mental domain was .82 and for the somatic domain was .85, whereas the same for Marathi was .83 for mental domain and .88 for the somatic domain. It was hence found validated and a reliable tool for assessing the QoL of hypertensive patients.

Estimation of Face Validity and Reliability of the Questionnaire

The questionnaire was pretested (n = 10, in individuals known to the investigator) and piloted (n = 50, in individuals not known to the investigator) by the researcher using the interview method. The questions were asked in the language best understood by the respondent (English, Hindi, or Marathi) for checking the face validity of the questionnaire.[19]

Flow of Study for Data Collection

Data Collection Using MINICHAL Scale

The MINICHAL questionnaire on HR-QoL included data on signs and symptoms of hypertension, duration of hypertension, and number of drugs prescribed consumed by patients. Hence the patients included were the ones who were previously diagnosed with hypertension and were a part of the routine follow ups. Patients were classified into two groups in terms of blood pressure control according to JNC8 criteria.[24] Patients with clinic systolic and diastolic greater than or equal to 140 and 90 mmHg, respectively, were classified as "uncontrolled" hypertensive patients and those with systolic and diastolic blood pressure lower than 140 and 90 mmHg, respectively, were classified as "controlled" hypertensive patients.

Measurement of Anthropometry

Demographic and physical details and anthropometric details were acquired in the clinic. Height was measured in centimeters using standard protocols using a standardized stadiometer (SECA) and the weight was measured in kilograms using a standardized digital weighing balance (Omron, Japan). The height, weight, waist circumference, and hip circumference were measured as per the NHANES protocols using the standard protocol in centimeters.[25] The weight was measured in their light clothes. Overcoats, jackets, wallet, watch, belt, heavy clothing, or personal items were removed before the weight was measured. The waist circumference was measured during exhalation at a point just above the hip bones while keeping the measuring tape parallel to the ground. The hip circumference was measured at widest point of the hips at the level and the waist to hip ratio was then calculated. The body mass index (BMI) was calculated as weight/(height)^2 and classified as per the World Health Organization cut-off points.[25]

Measurement of Blood Pressure

The measurement of blood pressure was done by a standard mercury sphygmomanometer using a standard size cuff or an adult large size cuff according to patient size.[26] The subjects were first explained the procedure and asked to rest in a supine position for 5 min in a quiet room at ambient temperature before the measurement was made. The brachial artery was located, and a cuff applied ensuring that it was at the

level of the heart. The cuff was inflated to 20 to 30 mmHg above the palpated systolic blood pressure. The column was lowered at a speed of 2 mm/s and blood pressure was noted to the nearest 2 mm. Readings were taken three times for each subject at a time interval of 5 min between readings. The average of these three readings was determined as the blood pressure of the subject.

Statistical Analysis

Statistical analysis was performed using SPSS software version 21.0.[27] The sample was categorized into controlled and uncontrolled hypertensive groups. Data is presented as mean ± standard deviation (SD) unless otherwise stated. Descriptive statistics were used for assessment of age, level of education, weight, height, BMI, waist circumference, hip circumference, and WHR along with systolic and diastolic blood pressure. A P-value ≤.05 was (with Bonferroni adjustments were done for multiple comparisons when required) considered significant.

Results

Demographics

The mean age of the participants was 47.0 ± 10.9 years. The majority of subjects (83%) were from semi-urban areas. Education group was based on the standard classification using the Kuppuswami socioeconomic scale, 2018 which defines 12th standard as an intermediate or post-high school diploma as basic education standard. Above 12 years of education it is classified as graduate and postgraduate or professionals or honors. The anthropometric details suggested that the mean weight of the study population was 71.9 ± 7.9 kg and the BMI was 25.8 ± 3.1 kg/m². About 40% of the patients were obese, with around 5% morbidly obese. The mean hip circumference was 87.3 ± 5.6 cm and the mean waist circumference was 82.1 ± 6.8 cm. The majority (94.8%) of the population had a WHR of 0.9 or above indicative of abdominal obesity, with a mean WHR of 0.94 ± 0.05. There was an increase in the waist circumference and WHR with the increasing BMI. It was found that The WHR of 0.93 was higher than the recommended WHR of 0.9 for Indians. Notably, this WHR is of the population with normal BMI. This indicates a high prevalence of android obesity in the population.

Blood pressure was not controlled in 62% (n = 312) of participants. There was an upward trend in the number of patients with uncontrolled hypertension with increasing age in the sample population (Table 1, $P < .001$, r = .8). The analysis of differences between the controlled and uncontrolled hypertensive groups indicated that the BMI of the uncontrolled hypertensive group was greater than that of the controlled blood pressure group. The number of uncontrolled hypertensive was highest in people with BMI range between 25.0 and 29.9 kg/m². The mean systolic blood

Table 1. Demographic and Anthropometric Data of the Participants.

Characteristics	Number of patients (%)
Age range (years)	
20-29	100 (20)
30-39	90 (18)
40-49	125 (35)
50-60	185 (37)
Education years	
>12	198 (39.6)
<12	302 (60.4)
Marital status	
Married	125 (25)
Single/divorced	375 (75)
Language spoken	
English	105 (21)
Hindi	45 (9)
Marathi	350 (70)

Table 2. Distribution of Controlled and Uncontrolled Hypertension.

Parameters	Controlled hypertension	Uncontrolled hypertension	P-value
Age (years)	42 ± 9.3	52 ± 8.0	.2
SBP	123 ± 6	151 ± 12	.001
DBP	84 ± 5	87 ± 6.0	.06
BMI	23.3 ± 2	28.4 ± 3.3	.07
WHR	0.91 ± 0.02	0.95 ± 0.06	.04

pressure among patients in the uncontrolled hypertension was 23 ± 8 mmHg higher than the controlled hypertensive group (Table 2). The diastolic blood pressure did not vary greatly between the two groups (Table 2). The average duration of hypertension, since diagnosis was 9 ± 3 years for both controlled and uncontrolled hypertension. The number of prescription medicines consumed by uncontrolled and controlled hypertensive were 4 ± 2 ($P > .3$) and 2 ± 1 ($P > .2$) respectively. Regression analysis indicated a significant relationship between the age of participants and increased systolic blood pressure levels. With an increase in 5 years after the age of 45 years, the systolic blood pressure rose by 8.1% among the uncontrolled hypertensive group, while in the controlled blood pressure group there was an increase of 3.2% in systolic blood pressure, which was considerably lower ($P < .001$) than the uncontrolled hypertensive group.

Quality of Life Among Hypertensive Patients

The responses in the MINICHAL scale (Table 3) showed that the mental health domain was more impaired than the somatic domain among patients with uncontrolled blood pressure.

Table 3. Responses to MINICHAL Scale.

	Uncontrolled hypertension				Controlled hypertension			
	No, not at all (n)	Yes, somewhat (n)	Yes, a lot (n)	Yes, very (n) much	No, not at all (n)	Yes, somewhat (n)	Yes, a lot (n)	Yes, very much (n)
Q1 Poor sleep	161	112	8	31	49	80	49	10
Q2 Difficulty to maintain social relations	52	186	48	26	37	103	40	8
Q3 Difficulty in interaction	42	131	113	26	25	77	83	3
Q4 Not playing useful role	17	78	189	28	9	67	67	45
Q5 Unable to make derision	24	98	172	10	13	89	92	2
Q6 Felt distressed continuously	31	55	205	21	15	29	70	74
Q7 Life is a struggle	12	42	187	71	24	49	106	9
Q8 Not enjoying daily activities	9	49	162	92	20	86	81	1
Q9 Felt worn out	4	29	203	76	14	23	151	0
Q10 Felt sick	1	13	213	85	2	24	158	4
Q11 Felt breathless	169	97	19	27	94	65	12	17
Q12 Swollen ankles	117	27	129	39	72	24	72	20
Q13 Frequent urination	23	61	221	7	9	32	92	55
Q14 Dry mouth	30	15	234	33	21	14	92	70
Q15 Chest pain without exertion	165	130	14	3	128	41	17	2
Q16 Tingling and numbness	25	22	178	87	16	22	133	17
Q17 Quality of life affected by hypertension and its treatment	28	5	215	64	13	9	136	30

Responses in the mental domain indicated that the uncontrolled blood pressure patients felt lethargic, slept poorly, were not able to maintain their social relationships, and were not able to play a useful role in family and society and further experienced a feeling of being distressed and worthless (Figure 1). A subjective feeling of not being well was seen in 67% of the patients. The overall HR-QoL score for participants with uncontrolled and controlled blood pressure was 41 ± 5 and 35 ± 4 ($P < .0001$) respectively. There was a significant difference between the average scores ($P < .001$) on the two domains between the two groups. The average scores for uncontrolled and controlled hypertensive on the mental plane were 2.8 ± 2.5 (95% CI=2.3-3.1) and 3.7 ± 1.3 (95% CI=1.5-2.2) respectively, whereas on the somatic domain scores were 3.4 ± 3.2 (95% CI=3.0-4.0) and 4.3 ± 3.0 (95% CI=2.0-2.8) respectively.

Out of 9 questions under the mental domain, the HR-QoL of uncontrolled and controlled blood pressure groups was significantly different in 7 and 6 questions, with most of participants responded to the questions as "yes very much" or "yes a lot." The patients in the uncontrolled hypertensive group complained of the feeling of being worn out on the most days of the week and were unable to pursue certain daily activities as well. They perceived life to be a struggle on a regular basis and felt that they were facing difficulties in maintaining their social relationships unlike before the diagnosis of the disease. They were constantly distraught and experienced the feeling of worthlessness which affected their social relationships. However, the patients in the controlled hypertensive group felt that they contributed significantly toward their family and toward their workplace. They were more comfortable in their social interactions, although they were equally distressed and worn out through most of the day.

It was also observed that the controlled hypertensive group coped much better than the uncontrolled hypertensive group on the somatic domain and the HR-QoL was significantly altered on only 4 aspects as compared to 6 aspects for uncontrolled hypertensive group. Most complaints on the physical domain were noted to occur after minimal exertion.

Discussion

This study showed hypertensive male patients with uncontrolled hypertension perceived their HR-QoL as poor compared to those with controlled blood pressure. In this study we identified that over 60% of patients attending an outpatient clinic for blood pressure management had uncontrolled blood pressure. Health related quality of life was reduced in those subjects with poorer blood pressure control showing that the mental domain was being affected more than the somatic domain. The feeling of being distraught was noted to be higher in the group of patients with uncontrolled blood pressure, which merits directing programs to improve QoL to drive better blood pressure control.

The control of hypertension requires therapeutic lifestyle changes which includes medicines and changes in the diet and exercise schedule. Al-Ghamdi et al[28] noted that though hypertension is seen as an asymptomatic condition, increasing number of symptoms on the physical domain including breathlessness, swollen ankles, and tingling numbness was a major determinant for HR-QoL of hypertensive patients. It is of merit to study further the impact of various symptoms as a determinant of HR-QoL.

The present study revealed that the higher number of uncontrolled hypertensive were overweight rather than obese, contrary to results from other earlier studies.[29,30] Previous studies showed a linear relationship between increased blood pressure and BMI,[31-34] although recent advances have indicated that raised blood pressure has multifactorial risk factors which are a combination of both modifiable and non-modifiable factors, obesity being one of the most important factors.[5,6,15,34-36] Possible considerations for higher blood pressure in people with overweight as compared to people with obesity could be due to better medication compliance, greater advice and guidance given to them regarding diet, or higher awareness that they have regarding blood pressure management, although this merits further analysis. Our study noted higher BMI in controlled hypertensive patients, although the HR-QoL was more impacted in uncontrolled hypertensive patients, indicating blood pressure to be a greater determining factor of HR-QoL, although further analysis is required to ascertain the same. However, studies by Poljičanin et al; Aduragbenro et al and have demonstrated that lower BMI, absence of comorbidities and health related complications have a positive impact on health related quality of life among hypertensives.[36-38]

In our study, a worse QoL score was observed in patients with higher systolic blood pressure suggestive of uncontrolled hypertension. The principal findings of this study indicated that uncontrolled hypertension poses an impact on the HR-QoL. It was noted that HR-QoL of participants with uncontrolled hypertension was impacted more as compared to the controlled hypertensive participants, on both the mental health and somatic planes, in line with a previous study.[34] It was observed that the mental domain was impacted more than the somatic domain and a feeling of distress and of not being able to play a useful role in the family was seen in those patients with uncontrolled blood pressure. A Swedish general population data of 45 000 individuals observed that anxiety/depression had the highest influence on patients perceived health.[39] However, certain reports of HR-QoL among hypertensive individuals have been inconsistent, where some studies find poorer HR-QoL among hypertensive patients compared to the general population[34,39,40] while a similar study by Moum et al[41] did not report any impact of hypertension on HR-QoL in some domains. The findings of the present study are in line with our previous work where we noted no difference in HRQoL in those with controlled blood pressure. The reduction in HRQoL seen in those with uncontrolled blood pressure was particularly evident in the mental health domain.[42] Poor nutritional status of the study population, with most participants being over-weight or obese may

also, at least in part, contributory to poor HRQoL.[21,43,44] It was observed that more than 40% of the respondents were obese in the present study and android obesity was prevalent among the participants which negatively affected the HRQoL scores. Similar results by Han et al and Hatami et al have been obtained in studies from Italy and Japan respectively which have suggested obesity as one of the major contributors for a poor HRQoL scores.[44-46]

The mean score for MINICHAL was higher for the present study compared to a previous study from Brazil by Han et al[46] suggesting poorer QoL of the study population. This may be attributed to higher score on the mental and somatic domain in this study. Previous studies have showed an altered score on the mental domain and have indicated that a poorer score on mental domain may contribute to mal adjustments in the society or a greater feeling of distress and a higher somatic score points toward higher number of symptoms experienced by hypertensives.[33,47] However, the HR-QoL was found to be significantly different among controlled and uncontrolled hypertensive for the two items of the mental domain questions that is, the continuous feeling of distress and the feeling of life is a struggle. It was observed that the respondents answered with a "Yes, very much" and "yes a lot" which indicated that apart from the physiological effect of the disease, the psychological impact was also an import factor affecting the health related quality of life. Similar findings were observed by Saleem et al and Gihl which suggested that psychological stress affected the quality of life and contention among the hypertensive.[48-50]

It may be of merit to monitor QoL levels over a longer period of time to assess the levels of perceived stress which may contribute to the development of hypertension in this population.[46]

This study has several strengths and limitations. To our knowledge this is the first study evaluating HRQoL in a representative sample of male patients with hypertension attending an Indian outpatient clinic with a focus on comparing controlled and uncontrolled hypertension. Furthermore, the MINICHAL scale, an HRQoL assessment tool tailored for hypertensive patients, was used in this study. Not only is this scale valid, but it is also more reliable and better at assessing HRQoL among patients with hypertension. However, this study has some limitations. One of the limitations of this study was that only male patients were recruited. Thus, we have to interpret the results cautiously within this context and further studies are required to assess whether there is an association between impaired QoL and blood pressure control in women. Another limitation is that no measure of medications prescribed or medication compliance was monitored, hence it is uncertain as to whether impaired HR-QoL and its association with blood pressure control is due to reduced medication adherence. The present study utilized manual blood pressure monitoring by a health professional using a mercury sphygmomanometer rather than using a blood pressure automated device. A recent meta-analysis demonstrated that automated office blood pressure readings were similar to the awake ambulatory blood pressure

readings and did not exhibit the "white coat effect" associated with routine office blood pressure measurement.[50] Furthermore, there are concerns about the use of mercury sphygmomanometers, as they are being phased out from use globally. However, it is justifiable for this study as the research was conducted in a hospital and the mercury-based instruments are still used to measure blood pressure of the patients. The findings cannot necessarily be generalized to the wider community as this study population was from a single center in urban India. Further multi-center studies with larger sample sizes are required in this direction with consideration for the types, dosage and frequency of medications consumed, as well as the physical activities are undertaken.

It can be concluded from this study, that people with uncontrolled hypertension have poorer QoL, especially presented as a feeling of distress when compared with controlled hypertensive patients. It is noted that the QoL is impacted on both the mental and somatic domains. The MINICHAL scale could be used as a tool for assessing the quality of life of hypertensive with lower MINICHAL scores conforming to better blood pressure control. The study recommends initiating health programs directed toward improving HR-QoL getting translated into better blood pressure control. The medical treatment should not be restricted to improve the clinical outcomes but also should be targeting the overall health and well-being of the patients. The implication of this study is to consider assessing the QoL of hypertensive patients regularly to elicit their perception of their quality of life and their social adjustment.

Author Contributions

Mansi Patil contributed to the study design and interpretation of results; data analysis, interpretation of results, and drafting the manuscript; Radhika Hedaoo contributed to reviewing the manuscript and editing and writing the manuscript; Gavin Lambert has contributing to writing and reviewing the manuscript. Rohan Shah, Syed M Tauseef, Roy M Marzo and Siew Mooi Ching have contributed toward formulating the study design, data analysis, and reviewing of the manuscript.

Declaration of Conflicting Interests

Funding

ORCID iDs

Mansi Patil https://orcid.org/0000-0002-2337-385X
Gavin Lambert https://orcid.org/0000-0003-0315-645X

References

1. ICMR. India: Health of Nation's States - The India State Level Disease Burden Initiative. 2017.

2. Arokiasamy P. India's escalating burden of non-communicable diseases. *Lancet Glob Health*. 2018;6(12):e1262-e1263. doi:10.1016/s2214-109x(18)30448-0

3. Gupta R, Gaur K, S Ram CV. Emerging trends in hypertension epidemiology in India. *J Hum Hypertens*. 2019;33(8):575-587. doi:10.1038/s41371-018-0117-3

4. Anchala R, Kannuri NK, Pant H, et al. Hypertension in India: a systematic review and meta-analysis of prevalence, awareness, and control of hypertension. *J Hypertens*. 2014;32(6):1170-1177. doi:10.1097/HJH.0000000000000146

5. Ghosh S, Kumar M. Prevalence and associated risk factors of hypertension among persons aged 15–49 in India: a cross-sectional study. *BMJ Open*. 2019;9:e029714. doi:10.1136/bmjopen-2019-029714

6. Bhatia M, Kumar M, Dixit P, Dwivedi LK. Diagnosis and treatment of hypertension among people aged 45 years and over in India: a sub-national analysis of the variation in performance of Indian states. *Front Public Health*. 2021;9:766458. doi:10.3389/fpubh.2021.766458

7. Patel S, Ram F, Parry C, Kumar Patel S. Associations of alcohol consumption with chronic diseases, lifestyle behaviors and socioeconomic-demographic characteristics in India. *Int J Alcohol Drug Res*. 2020;8(1):37-50. doi:10.7895/ijadr.259

8. World Health Organization. Indicator metadata registry details, n.d. Accessed December 15, 2022. https://www.who.int/data/gho/indicator-metadata-registry/imr-details/3155

9. Bhise MD, Patra S. Prevalence and correlates of hypertension in Maharashtra, India: a multilevel analysis. *PLoS One*. 2018;13(2):e0191948. doi:10.1371/journal.pone.0191948

10. Geevar Z, Krishnan MN, Venugopal K, et al. Prevalence, awareness, treatment, and control of hypertension in young adults (20-39 years) in Kerala, South India. *Front Cardiovasc Med*. 2022;9:765442. doi:10.3389/fcvm.2022.765442

11. World Health Organization. Hypertension, n.d. Accessed December 15, 2022. https://www.who.int/india/health-topics/hypertension

12. Prenissl J, Manne-Goehler J, Jaacks LM, et al. Hypertension screening, awareness, treatment, and control in India: A nationally representative cross-sectional study among individuals aged 15 to 49 years. *PLoS Med*. 2019;16(5):e1002801. doi:10.1371/journal.pmed.1002801

13. Akujobihenry C. Comparative study of quality of life between controlled and uncontrolled blood pressure hypertensives in family practice of Lagos University teaching hospital. *Lagos*. 2014.

14. Lee CJ, Park WJ, Suh JW, et al. Relationship between health-related quality of life and blood pressure control in patients with uncontrolled hypertension. *J Clin Hypertens*. 2020;22(8):1415-1424. doi:10.1111/jch.13941

15. Orley J. Quality of life: the WHOQOL. *Eur Psychiatry*. 1996;11:228s. doi:10.1016/0924-9338(96)88679-2 4

16. Soutello A, Rodrigues R, Jannuzzi F, et al. Quality of life on arterial hypertension: validity of known groups of MINICHAL. *Arq Bras Cardiol*. 2015. doi:10.5935/abc.20150009

17. Melchiors AC, Correr CJ, Pontarolo R, Santos FDODS, Souza RADPE. Qualidade de vida em pacientes hipertensos e validade concorrente do Minichal-Brasil. *Arq Bras Cardiol*. 2010;94(3):357-364. doi:10.1590/s0066-782x2010000300013

18. Shah R, Patel J, Shah A, Desai G, Buch J. Determinants of health-related quality of life in patients with hypertension. *Natl J Physiol Pharm Pharmacol*. 2020;10(4):1. doi:10.5455/njppp.2020.10.02031202011022020

19. Roca-Cusachs A, Dalfó A, Badia X, Arístegui I, Roset M. Relation between clinical and therapeutic variables and quality of life in hypertension. *J Hypertens*. 2001;19(10):1913-1919. doi:10.1097/00004872-200110000-00028

20. Didem A, Unal A, Alaettin U, Mustafa T. Prevalence of hypertension among individuals aged 50 years and over and its impact on health related quality of life in a semi-rural area of western Turkey. *Chin Med J*. 2008;121(16):1524-1531. doi:10.1097/00029330-200808020-00005

21. Lambert GW, Hering D, Esler MD, et al. Health-related quality of life after renal denervation in patients with treatment-resistant hypertension. *Hypertension*. 2012;60(6):1479-1484. doi:10.1161/hypertensionaha.112.200865

22. Kindermann I, Wedegärtner SM, Mahfoud F, et al. Improvement in health-related quality of life after renal sympathetic denervation in real-world hypertensive patients: 12-month outcomes in the Global Symplicity Registry. *J Clin Hypertens*. 2017;19(9):833-839. doi:10.1111/jch.13007

23. Stewart AL. Functional status and well-being of patients with chronic conditions. Results from the Medical Outcomes Study. *J Am Med Assoc*. 1989;262(7):907-913. doi:10.1001/jama.262.7.907

24. Hernandez-Vila E. A review of the JNC 8 blood pressure guideline. *Tex Heart Inst J*. 2015;42(3):226-228. doi:10.14503/thij-15-5067

25. National Health and Nutrition Examination Survey, CDC. Anthropometry Procedures Manual. 2007, pp.37-39.

26. Elliott WJ. Recommendations for blood pressure measurement in humans and experimental animals: Part 1. Blood pressure measurement in humans. A statement for professionals from the subcommittee of Professional and Public Education of the American Heart Association Council on High Blood pressure ResearchPickering TG, Hall JE, Appel LJ, et al (American Heart Assoc, Dallas) Hypertension 45:142-161, 2005. *Yearb Cardiol*. 2006;2006:3-4. doi:10.1016/s0145-4145(07)70004-7

27. IBM Corp. IBM SPSS Statistics for Windows, Version 21.0. 2012. Armonk, NY: IBM Corp.

28. Al-Ghamdi MS, Taha AZ, Ahmad B, Khalil MS. Quality of life in a sample of hypertensive patients attending primary health care facilities in Al-khobar, saudi arabia. *J Fam Community Med*. 2002;9(1):25-32.

29. Bramlage P, Pittrow D, Wittchen HU, et al. Hypertension in overweight and obese primary care patients is highly prevalent and poorly controlled. *Am J Hypertens*. 2004;17(10):904-910. doi:10.1016/j.amjhyper.2004.05.017

30. Mannan A, Akter KM, Akter F, et al. Association between comorbidity and health-related quality of life in a hypertensive population: a hospital-based study in Bangladesh. *BMC Public Health*. 2022;22:1-12. doi:10.1186/s12889-022-12562-w

31. Brown CD, Higgins M, Donato KA, et al. Body Mass Index and the prevalence of hypertension and dyslipidemia. *Obes Res*. 2000;8(9):605-619. doi:10.1038/oby.2000.79

32. Zhang L, Guo X, Zhang J, et al. Health-related quality of life among adults with and without hypertension: A population-based

survey using EQ-5D in Shandong, China. *Sci Rep*. 2017;7:14960. doi:10.1038/s41598-017-15083-4

33. Lockhart P, Sun Y. Diseases of the cardiovascular system. In: Lockhart PB & Sun YP *Burket's Oral Medicine*. Wiley Online Library, 2021:505-552.

34. Ye R, Liu K, Zhang Z, Gong S, Chen X. Health-related quality of life of hypertension in China: a systematic review and meta-analysis. *J Cardiovasc Med*. 2018;19:430-438. doi:10.2459/jcm.0000000000000678

35. Dave Y, Sorani D, Patel M. Cross cultural adaptation, translation, validation and reliability analysis of Gujarati version of Hypertension Quality of Life Questionnaire (MINICHAL). *Int J Health Sci Res*. 2021;11(10):10-16. doi:10.52403/ijhsr.20211003

36. Marques da Silva P, Haag U, Guest JF, Brazier JE, Soro M. Health-related quality of life impact of a triple combination of olmesartan medoxomil, amlodipine besylate and hydrochlorotiazide in subjects with hypertension. *Health Qual Life Outcomes*. 2015;13:1–13. doi:10.1186/s12955-015-0216-6

37. Poljičanin T, Ajduković D, Šekerija M, Pibernik-Okanović M, Metelko , Vuletić Mavrinac G. Diabetes mellitus and hypertension have comparable adverse effects on health-related quality of life. *BMC Public Health*. 2010;10:1–6. doi:10.1186/1471-2458-10-12

38. Adedapo AD, Akunne OO, Adedokun BO. Comparative assessment of determinants of health-related quality of life in hypertensive patients and normal population in south-west nigeria. *Int J Clin Pharmacol Ther*. 2015;53(3):265-271. doi:10.5414/cp202257

39. Burström K, Sun S, Gerdtham U-G, et al. Swedish experience-based value sets for EQ-5D Health States. *Qual Life Res*. 2014;23(2):431-442. doi:10.1007/s11136-013-0496-4

40. Gupta K. Prevalence of hypertension and risk factors among young Indians. *Indian Heart J*. 2018;70:S10. doi:10.1016/j.ihj.2018.10.397

41. Moum T, Naess S, Sørensen T, Tambs K, Holmen J. Hypertension labelling, life events and psychological well-being. *Psychol Med*. 1990;20(3):635-646. doi:10.1017/s0033291700017153

42. Xiao M, Zhang F, Xiao N, Bu X, Tang X, Long Q. Health-related quality of life of hypertension patients: a population-based cross-sectional study in Chongqing, China. *Int J Environ Res Public Health*. 2019;16(13):2348. doi:10.3390/ijerph16132348

43. Xu X, Rao Y, Shi Z, Liu L, Chen C, Zhao Y. Hypertension impact on health-related quality of life: A cross-sectional survey among middle-aged adults in Chongqing, China. *Int J Hypertens*. 2016;2016:7404957. doi:10.1155/2016/7404957

44. Verma A, Patyal A. Metabolic syndrome among hypertensive patients: prevalence and associated risk factors among adults of southern Rajasthan, India. *J Hypertens*. 2021;39 (Supplement 1):e245-e246. doi:10.1097/01.hjh.0000747240.04041.6f

45. Singh S, Shankar R, Singh GP. Prevalence and associated risk factors of hypertension: a cross-sectional study in urban Varanasi. *Int J Hypertens*. 2017;2017:5491838-5491910. doi:10.1155/2017/5491838

46. Han JH, Park HS, Shin CI, et al. Metabolic syndrome and quality of life (QOL) using generalised and obesity-specific qol Scales. *Int J Clin Pract*. 2009;63(5):735-741. doi:10.1111/j.1742-1241.2009.02021.x

47. Hatami H, Deihim T, Amiri P, Cheraghi L, Azizi F. Association between metabolic syndrome and health-related quality of life among individuals with normal and impaired glucose regulation: findings from Tehran lipid and glucose study. *Arch Iran Med*. 2016;19(8):577-583.

48. Sinval J, Sirgy MJ, Lee DJ, Marôco J. The quality of Work Life Scale: validity evidence from Brazil and Portugal. *Appl Res Qual Life*. 2020;15(5):1323-1351. doi:10.1007/s11482-019-09730-3

49. Saleem F, Hassali MA, Shafie AA. A cross-sectional assessment of health-related quality of life (hrqol) among hypertensive patients in Pakistan. *Health Expect*. 2014;17(3):388-395. doi:10.1111/j.1369-7625.2012.00765.x

50. Gihl A. Health-related quality of life in pulmonary arterial hypertension. *Adv Pulm Hypertens*. 2010;8(4):215-222. doi:10.21693/1933-088x-8.4.215